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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,077	06/23/2003	Stephen Suffin	10701-006-999	1225

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MEDLEN & CARROLL, LLP
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EXAMINER

JONES, DAMERON LEVEST

ART UNIT	PAPER NUMBER
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1618

MAIL DATE	DELIVERY MODE
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10/26/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/602,077	Applicant(s) SUFFIN, STEPHEN	
	Examiner D. L. Jones	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/12/07 & 8/20/07.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-42 and 50-60 is/are pending in the application.
- 4a) Of the above claim(s) 57-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-42 and 50-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

ACKNOWLEDGMENTS

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/20/07 has been entered.

2. The Examiner acknowledges receipt of the amendment filed 7/12/07 wherein claims 1-39 and 43-49 are canceled and claims 40, 42, 54, and 56 are pending.

Note: Claims 40-42 and 50-60 are pending.

RESPONSE TO APPLICANT'S AMENDMENT/ARGUMENTS

3. The Applicant's arguments and/or amendment filed 7/12/07 to the rejection of the claims made by the Examiner under 35 USC 102 and/or double patenting have been fully considered and deemed persuasive for reasons of record in Applicant's response. Therefore, the said rejections are hereby withdrawn.

WITHDRAWN CLAIMS

4. Claims 57-60 are withdrawn from consideration as being directed to a non-elected invention (see 37 CFR 1.142(b) and MPEP 821.03).

NEW GROUNDS OF REJECTION

102 Rejection

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 40-42 and 50-56 are rejected under 35 U.S.C. 102(b) as being anticipated by Wenk et al (The Journal of Neuroscience, October 1994, Vol. 14, No. 10, pp. 5986-5995).

Wenk et al disclose the behavioral, histological, and electrophysiological effects of 192 IgG-saporin injections into the basal forebrain of rats. Electroencephalographic (EEG) recordings were taken from the lesioned rats before and during treatment with scopolamine. Histological and biochemical investigations confirmed the effectiveness and specificity of the 192 IgG-saporin (see entire document, especially, page 5986, summary). The basal forebrain region includes the medial septum, vertical and horizontal limbs of the diagonal band of Broca, and the nucleus basalis magnocellularis (page 5986, right column, second complete paragraph). The basal forebrain region of subjects was microinfused with a small amount of 192 IgG-saporin. An EEG spectral analysis was conducted. The brains of the subjects were analyzed by various neurochemical and histological methods to confirm the effectiveness and selectivity of the lesions produced by 192 IgG-saporin (page 5987, left column, second complete paragraph).

An unilateral lesion study was conducted. The results of the studies guided the choice of lesion coordinates for other studies (i.e., behavioral studies). The study determined the optimal concentration of 192 IgG-saporin necessary to destroy the greatest number of cholinergic cells in the horizontal limb of the diagonal band of Broca, the dorsal and ventral aspects of the basal ganglia, and other surrounding structures. The unilateral lesion coordinates were posterior to bregma, lateral from the midline, and below the dura for all the subjects (page 5987, right column, first complete paragraph). Behavioral studies were conducted wherein bilateral lesion coordinates posterior to the bregma, lateral from the midline, and below the dura were utilized (page 5987, right column, second complete paragraph).

Electrophysiology studies were performed. Each subject had multiple EEG recordings taken. Total (absolute) power was determined for the delta (1-4 Hz), theta (4-8 Hz), alpha (8-12 Hz), and beta (12-20 Hz) bands. In subjects with unilateral lesions, recordings were completed immediately before and 20-30 minutes after and intraperitoneal injection of scopolamine HCl. The data were analyzed by ANOVA and comparisons were made by Duncan's multiple range and Newman-Keuls tests (page 5988, left column, 'Electrophysiology'; page 5989, left column, 'Electrophysiology'). On page 5989, Figure 1, Figure 2, and Table 1 disclose comparison data for the subjects.

Thus, both Applicant and the cited prior art discloses a method of determining medication efficacy having the steps as set forth in independent claims 40 and 54 wherein multiple EEG recordings are obtained, the multivariate outcome measurement is derived from a frequency band selected from delta, theta, alpha, and beta, and a


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medication is administered and one or more EEG recordings obtained therefrom, and eventually, the comparison of the data from the subjects.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



D. L. Jones
Primary Examiner
Art Unit 1618

October 22, 2007